

product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MYCAMINE (mycalfungin sodium). MYCAMINE is indicated for treatment of patients with esophageal candidiasis and prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for MYCAMINE (U.S. Patent Nos. 6,107,458 and 6,265,536) from Astellas Pharma, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated February 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MYCAMINE represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MYCAMINE is 2,546 days. Of this time, 2,221 days occurred during the testing phase of the regulatory review period, while 325 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* March 29, 1998. The applicant claims June 30, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 29, 1998, which was 30 days after FDA receipt of the original IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* April 26, 2004. The applicant claims April 23, 2004, as the date the new drug application (NDA) for MYCAMINE (NDA 21-754) was initially submitted. However, FDA records indicate that NDA 21-754 was initially submitted on April 26, 2004.

3. *The date the application was approved:* March 16, 2005. FDA has verified the applicant's claim that NDA 21-754 was approved on March 16, 2005.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 476 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and ask for a redetermination by November 20, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 19, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 11, 2006.

Jane A. Axelrad,
Associate Director for Policy, Center for Drug
Evaluation and Research.
[FR Doc. 06-7985 Filed 9-19-06; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E-0033]

Determination of Regulatory Review Period for Purposes of Patent Extension; APTIVUS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for APTIVUS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug

Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product CYDECTIN (moxidectin). CYDECTIN is indicated for the treatment and control of certain internal and external parasites in cattle. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CYDECTIN (U.S. Patent No. 4,916,154) from American Cyanamid Company, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 6, 2004, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of CYDECTIN represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CYDECTIN is 2,857 days. Of this time, 2,841 days occurred during the testing

phase of the regulatory review period, while 16 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)) involving this animal drug product became effective:* April 5, 1990. The applicant claims April 9, 1990, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was April 5, 1990, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act:* January 13, 1998. The applicant claims August 8, 1995, as the date the new animal drug application (NADA) for CYDECTIN (NADA 141-099) was initially submitted. The applicant claims this is the date it submitted the first component of NADA 141-099, which was submitted in several modules. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141-099 was January 13, 1998, which is considered to be the initially submitted date for NADA 141-099.

3. *The date the application was approved:* January 28, 1998. FDA has verified the applicant's claim that NADA 141-099 was approved on January 28, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,754 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments and ask for a redetermination by November 20, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 19, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions are to be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 1, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 06-7800 Filed 9-19-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2006E-0023 and 2006E-0345]

Determination of Regulatory Review Period for Purposes of Patent Extension; MYCAMINE—New Drug Application 21-754

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MYCAMINE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

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